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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,409	04/23/2008	Hans Gronlund	1768-139	4548

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
11/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/554,409	GRONLUND ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *22-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicant's amendment filed on 07/21/2009 is acknowledged.

2. Claims 22-41 are pending.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 22-33 and 37-38, directed to a recombinant Fel d 1 fusion product comprising a Fel d 1 chain I, a Fel d 1 chain 2 and a linker selected from a carbon-nitrogen bond or a peptide linker consisting of from 1 to 9 amino acid residues which links the N-terminal amino acid of one chain to the C-terminal amino acid of the other chain, pharmaceutical compositions and kits thereof.

II. Claims 34-36 and 40-41, directed to DNA sequences encoding a recombinant Fel d 1 fusion product comprising a Fel d 1 chain I, a Fel d 1 chain 2 and a linker selected from a carbon-nitrogen bond or a peptide linker having from 1 to 9 amino acid residues which links the

N-terminal amino acid of one chain to the C-terminal amino acid of the other chain III, expression vectors and hosts thereof and a method for making the fusion product.

III. Claim 39, directed to a method for diagnosing cat allergy comprising the step of combining a sample taken from a subject with a recombinant Fel d 1 fusion product comprising a Fel d 1 chain I, a Fel d 1 chain 2 and a linker selected from a carbon-nitrogen bond or a peptide linker having from 1 to 9 amino acid residues which links the N-terminal amino acid of one chain to the C-terminal amino acid of the other chain.

5. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defines the contribution over the prior art of Vailes et al. (IDS filed on 03/22/2007) in view of George et al. (PTO-892; Reference U).

Vailes et al. teaches a recombinant Fel d 1 fusion product comprising a Fel d 1 chain 1 and a Fel d 1 chain 2 wherein the N-terminal amino acid of chain 2 is linked to the C-terminal amino acid of the chain 1 by way of a 19 amino acid linker (In particular, Figure 1, 'Expression of Feld1 in baculovirus-infected insect cells' section on page 758, whole document).

The claimed invention differs from the prior art in the recitation of "a peptide linker

consisting of 1 to 9 amino acid residues."

Georger et al. teaches that small and medium oligopeptide linkers consisting of 1 to 14 amino acids may be used to link chimeric proteins. The reference teaches that the linker length influences the desired function of the chimeric proteins and provides a scaffold to prevent unfavorable interactions between the two domains. The reference specifically teaches the use of many particular linkers of 9 or fewer amino acids, particularly many dyad linkers (In particular, whole document, Table II, paragraph spanning columns on page 875, Table VII).

It would have been obvious to one of ordinary skill in the art at the time of invention to substitute a 1 to 9 amino acid linker in the recombinant Fel d 1 fusion product comprising a Fel d 1 chain 1 and a Fel d 1 chain 2 wherein the N-terminal amino acid of chain 2 is linked to the C-terminal amino acid of the chain 1 by way of a 19 amino acid linker because George et al. teaches that linker length may be optimized for function and the prevention of unfavorable interactions between the protein domains being linked. It would have been obvious to determine the optimal linker length to link the recombinant Fel d 1 fusion product of Vailes et al. and George et al. teaches that many dyad linkers are useful in chimeric proteins.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the

contrary.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 9, 2009
Nora M. Rooney
Patent Examiner
Technology Center 1600

/Nora M Rooney/

Examiner, Art Unit 1644